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EXHIBIT C



The opinion in support of the decision being
entered today is not binding precedent of the Board

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

MAILED

STEVEN C. QUAY
Junior Party,
(Patent 5,558,854),

AUG 29 2001

PAT & TM OFFICE
BOARD OF PATENT APPEALS
AND INTERFERENCES

v.

ERNEST G. SCHUTT, DAVID P. EVITTS,
RENE ALTA KINNER, CHARLES DAVID ANDERSON
and JEFFREY G. WEERS
Senior Party,
(Application 08/785,007).

Patent Interference No. 104,428

Before. McKELVEY, Senior Administrative Patent Judge, and SCHAFER and TIERNEY,
Administrative Patent Judges.

TIERNEY, Administrative Patent Judge.

MEMORANDUM OPINION and FINAL JUDGMENT
(Decision on Preliminary Motions)

This interference is before a motions panel for a decision on preliminary motions. Oral
argument took place on July 18, 2001. Present at oral argument for Junior Party Quay was Boris
Haskell, Esq. Senior Party Schutt was represented by Alton D. Rollins, Esq. and Charles L.
Gholz, Esq.

TABLE OF CONTENTS

I.	Findings of Fact	1
A.	The Interference	1
B.	The Junior Party	2
C.	The Senior Party	2
D.	Disclosures of the Application and Patent Involved in the Interference	3
1.	Quay '854 Patent	3
2.	Schutt '007 Application	5
E.	The Count	9
II.	Opinion	11
A.	Overview of Preliminary Motions	11
1.	Schutt Preliminary Motion 1	12
2.	Quay Preliminary Motion 1	17
3.	Schutt Preliminary Motion 2	18
4.	Quay Preliminary Motion 4	20
5.	Schutt Miscellaneous Motion 3 and Preliminary Motion 4	29
6.	Quay Preliminary Motions 2 and 3	31
7.	Quay Preliminary Motions 5 and 6	32
8.	Quay Preliminary Motions 7 and 8	33
9.	Quay Miscellaneous Motion 9 (Motion to Suppress)	33
III.	Order	34

Summary of the Opinion

This interference is directed to ultrasound contrast media compositions. These compositions are said to enhance the contrast in ultrasound images that are generated for medical diagnosis. In particular, this interference involves contrast media compositions which contain gaseous perfluorohexane.

As apparent from the Oral Hearing of July 18, 2001, both parties have admitted that they do not have *ipsis verbis* support for the breadth of the claims presently involved in the interference. Furthermore, neither party was able to sufficiently demonstrate that one skilled in the art would be guided or directed by their respective specifications, including their "original claims," to the inventions now claimed. Accordingly, we find that both parties claims are unpatentable under the written description requirement of 35 U.S.C. §112, first paragraph. As neither party has any pending or proposed claim that is patentable to that party, this decision on motions becomes a final decision.

I. Findings of Fact

The record supports, by a preponderance of the evidence, the following findings.

A. The Interference

1 The interference involves Quay, U.S. Patent No. 5,558,854 (Quay '854) versus Schutt et al., U.S. Application 08/785,007 (Schutt '007). (Paper No. 1 "Notice Declaring Interference"). Quay is the junior party and Schutt is the senior party.

B. The Junior Party

2. Sonus Pharmaceuticals, Inc. is the real party in interest in Quay '854, issued on September 24, 1996. (Quay Designation of Real Party in Interest, Paper No. 7, p. 1). Quay '854 issued from U.S. application 08/380,085 (Quay '085 application) filed on January 30, 1995. (Quay '854, QX 2001, front page). Quay '854 is said to be:

- (i) A divisional of U.S. Application No. 07/936,011, filed September 2, 1992, now abandoned.
- (ii) A continuation-in-part of U.S. Application No. 07/893,657, filed June 5, 1992, now U.S. Patent No. 5,409,688, issued April 25, 1995.
- (iii) A continuation-in-part of U.S. Application No. 07/761,311, filed September 17, 1991, now abandoned.

(QX 2001, front page). Quay was not accorded priority benefit for these applications.

C. The Senior Party

3. Alliance Pharmaceutical Corp. is the real party in interest in Schutt '007 which was filed on January 17, 1997. (Schutt's Supplemental 37 CFR §1.602(b) Notice, Paper No. 12, p. 1 and '007 File Jacket, QX 2010, p. 1). For purposes of priority, Schutt '007 has been accorded the benefit of the filing dates of:

- (i) U.S. Application No. 08/405,447 ("Schutt '447"), filed March 16, 1995, now U.S. Patent No. 5,639,443, issued June 17, 1997.
- (ii) U.S. Application No. 08/099,951, filed July 30, 1993, now abandoned.

(Paper No. 1, p. 31).

D. Disclosures of the Application and Patent Involved in the Interference

1. Quay '854 Patent

4. Quay '854 is said to describe contrast media compositions for ultrasound imaging.

According to Quay '854, ultrasound imaging employs waves of sound energy at frequencies above that discernable by the human ear. These waves can be reflected as they pass through the body with the different body tissues reflecting the ultrasound waves differently. These reflections can be detected and converted electronically into a visual display for medical diagnosis. (QX 2001, col. 1, lines 33-45).

5. Quay states that for some medical conditions, obtaining a useful ultrasound image of an organ or structure of interest can be especially difficult because the details of the structure may not be adequately discernible from the surrounding tissue absent a contrast-enhancing agent. (QX 2001, col. 1, lines 46-52, emphasis added). In an effort to provide improved imaging capabilities, Quay's invention "relates to agents that enhance the contrast in an ultrasound image generated for use in medical diagnosis." (QX 2001, col. 1, lines 15-17).

6. The ultrasound contrast-enhancing media described by Quay '854 are said to comprise microbubbles, composed of *biocompatible gases*, which are sufficiently small such that they pass through the pulmonary capillary and thereby allow contrast-enhanced ultrasound diagnosis of the left chambers of the heart. (QX 2001, col. 2, lines 59-65). Moreover, the free gas microbubbles of Quay '854 are said to "survive in the bloodstream long enough that they may be peripherally intravenously infused, travel through the right heart, through the lungs, and into the left cardiac

chambers without dissolving into solution.” (QX 2001, col. 2, line 65 to col. 3, line 2).

7. Quay defines the term “biocompatible gases” as follows:

By using the term “biocompatible gas” I mean a chemical entity which is capable of performing its function within or upon a living organism in an acceptable manner, without undue toxicity or physiological or pharmacological effects, and which is, at the temperature of the living organism, in a state of matter distinguished from the solid or liquid states by very low density and viscosity, relatively great expansion and contraction with changes in pressure and temperature, and the spontaneous tendency to become distributed uniformly throughout any container.

(QX 2001, col. 3, lines 21-30, emphasis added).

8. In identifying those gases that are effective biocompatible gases, Quay sets forth a coefficient Q that is said to describe the stability of microbubbles composed of a gas X in a given liquid. (QX 2001, col. 11, line 64 to col. 12, line 6). Quay indicates that gases having higher Q-values are promising with Q-values of greater than 5 being the most promising. (QX 2001, col. 17, lines 34-36). Quay provides Table IV that contains series of approximately 180 gases that have an estimated Q-value of 5 or greater. (QX 2001, Table IV). Perfluorohexane is not mentioned among the gases presented in Table IV.

9. Quay '854 contains several examples. In particular, Quay Example 6 is said to have tested the relationship of the state of matter of a given chemical entity with a high Q-coefficient and its utility as an ultrasound contrast agent. (QX 2001, Example 6, col. 21, lines 6-8). Specifically, Quay Example 6 describes a comparison of the ultrasound contrasting efficiencies

of perfluoropentane and perfluorohexane. At standard pressure and the body temperature of a human, based on boiling points, perfluoropentane is said to be a gas whereas perfluorohexane is said to be a liquid. (QX 2001, Example 6, col. 21, lines 13-19). In conducting the test, Quay determined that:

Less than 1.0 mL of the perfluoropentane dispersion, when mixed with the simulated blood, produced an extremely bright ultrasound signal which persisted for at least 30 minutes. A 1:10,000 dilution was still detectable.

In contrast, a 1.0 mL sample of the perfluorohexane dispersion was undetectable by ultrasound scanning under the same conditions, as was even a 10 mL sample (1:100 dilution).

The conclusion to be drawn is that both a high O-coefficient and a gaseous state at the body temperature of the organism being scanned is necessary for a substance to be effective as an ultrasound contrast agent according to the method that is the subject matter of this invention.

(QX 2001, Example 6, col. 21, lines 26-38, emphasis added).

2. Schutt '007 Application

10. Schutt '007 is directed to ultrasound contrast enhancement agents said to have prolonged longevity in vivo. (Schutt, U.S. Patent No. 5,639,443, QX 2009, col. 2, lines 50-52).¹ Schutt states that bubbles are the most efficient ultrasound contrast agents. Unfortunately, the small bubbles required to pass through capillaries possess a short lifetime. (QX 2009, col. 6, lines 53-58) According to Schutt, the contrast agents of the invention have a prolonged longevity and consist of virtually any conventional microbubble formulation where the gases inside the microbubble are selected based upon the partial pressures of the gases both inside and outside of

¹As noted at the Oral Hearing, Schutt '007 is a continuation of Schutt's '447 application, which issued as U.S. Patent No. 5,639,443 ("Schutt '443") Schutt '443 has been admitted in evidence as Exhibit QX 2009. For ease of reference, in discussing the specification of Schutt '007, the parties have generally cited to the corresponding portions of the Schutt '443 patent.

the bubble, and on the resulting differences in gas osmotic pressure that oppose bubble shrinkage. (QX 2009, col. 2, lines 52-57).

11. Schutt recognizes that a *“major aspect of the present invention is the selection of the gas phase.”* (QX 2009, col. 13, lines 35-36, emphasis added). Specifically, gases that possess a low vapor pressure and limited solubility in blood or serum (i.e., relatively hydrophobic) are advantageously provided in combination with another gas that is more rapidly exchanged with gases present in normal blood or serum. (QX 2009, col. 2, lines 57-62).

12. In an effort to stabilize the bubbles, Schutt’s gas filled microbubble preparations are said to comprise a mixture of a first gas or gases and a second gas or gases within generally spherical membranes with the terms “gas” and “vapor” being used interchangeably. (QX 2009, col. 2, line 65 to col. 3, line 1 and col. 6, lines 8-9). Schutt ‘007 defines the first and second gases as follows:

[T]he first gas and the second gas are respectively present [1] in a molar ratio of about 1:100 to about 1000:1, and wherein [2] the first gas has a vapor pressure of at least about $(760-x)$ mm Hg at 37 °C., where x is the vapor pressure of the second gas at 37 °C., and wherein [3] the vapor pressure of each of the first and second gases is greater than about 75 mm Hg at 37 °C., with the proviso that [4] the first gas and the second gas are not water vapor.

(QX 2009, col. 3, lines 1-8, bolded numbers added for emphasis).

13. Schutt also defines the gases in terms of their osmotic pressure. Specifically, Schutt “surprisingly discovered” that gases and gas vapor mixtures that exert a gas osmotic pressure can

greatly retard the collapse of small diameter bubbles. (QX 2009, col. 7, lines 6-9). As stated by

Schutt:

The present invention includes the discovery that a single gas or a combination of gases can together act to stabilize the structure of the microbubbles entraining or entrapping them. Essentially, *the invention utilizes a first gas* or gases (a "primary modifier gas") that optionally is ordinarily present in normal blood and serum *in combination with one or more additional second gases* (a "gas osmotic agent or agents" or a "secondary gas") that act to regulate the osmotic pressure within the bubble. Through regulating the osmotic pressure of the bubble, the gas osmotic agent (defined herein as a single or mixture of chemical entities) exerts pressure within the bubble, aiding in preventing deflation.

(QX 2009, col. 8, lines 10-18, emphasis added). Moreover, Schutt states:

In general, the invention uses a *primary modifier gas* or mixture of gases that dilute a *gas osmotic agent* to a partial pressure less than the gas osmotic agent's vapor pressure until the modifier gas will exchange with gases normally present in the external medium. The gas osmotic agent or agents are generally relatively hydrophobic and relatively bubble membrane impermeable and also further possess the ability to develop gas osmotic pressures greater than 75 or 100 Torr at a relatively low vapor pressure.

(QX 2009, col. 7, lines 9-13, emphasis added).

14. In selecting the primary modifier gas, Schutt discloses:

However, the modifier gas *must be* capable of diluting and maintaining the gas osmotic agent or agents at a partial pressure below the vapor pressure of the gas osmotic agent or agents while the gases in blood or other surrounding liquid diffuse into the bubble.

(QX 2009, col. 8, lines 20-24, emphasis added). Furthermore, Schutt's limits the selection of the modifier and osmotic gases as follows:

In an aqueous medium, water vapor is not considered to be one of the "gases" in question. Similarly, when microbubbles are in a nonaqueous liquid medium, the vapor of that medium is not considered to be one of the "gases."

(QX 2009, col. 8, lines 24-28).

15. With respect to the osmotic gas, Schutt '007 teaches that it is important that perfluorocarbon osmotic gases do not condense at the partial pressure present in the bubbles and at body temperature. (QX 2009, col. 14, lines 10-13). According to Schutt, perfluorocarbons having a vapor pressure of greater than 80 mm Hg at 37 °C and eight or less carbon atoms are preferred. (QX 2009, col. 14, lines 30-32). Moreover, out of seven "representative" fluorocarbons meeting the criteria, perfluorohexane had the highest ability to stabilize the microbubbles. (QX 2009, col. 14, lines 24-29).

16 Schutt '007 Examples 1, 2, 3, 4, 5, 6 and 9 describe the testing of microbubbles where perfluorohexane was employed as the osmotic gas agent. For instance, Schutt '007 Example 1 describes the preparation of microbubbles through sonification and states that "air [was used] as a modifier gas and perfluorohexane as the gas osmotic agent." (QX 2009, Example 1, col. 19, lines 8-15).

17. The Schutt '007 application was filed on January 17, 1997 as a continuation application under 37 C.F.R. § 1.60 of the Schutt '447 application, which issued as the Schutt '443 patent.

Claim 1 of the Schutt '007 application read as follows

1. A stabilized gas filled microbubble preparation, comprising:
a mixture of a first gas or gases and a second gas or gases within generally spherical membranes to form microbubbles, wherein said first gas and said second gas are respectively present in a molar ratio of about 1:100 to about 1000:1, and wherein said first gas has a vapor pressure of at least about $(760 - x)$ mm Hg at 37 °C, where x is the vapor pressure of the second gas at 37 °C, and wherein said vapor pressure of each of said first and second gases is greater than about 75 mm Hg at 37 °C, with the proviso that said first gas and said second gas are not water vapor.

18. Concurrent with the filing of the Schutt '007 application, Schutt filed a preliminary amendment canceling all original claims and adding the following new claims 62-64:

- 62. A composition for echogenic microbubbles in a liquid medium, wherein the microbubbles contain the vapor of a fluorocarbon that is a liquid at body temperature.
- 63. A composition of echogenic microbubbles in a liquid medium, wherein the microbubbles contain perfluorohexane vapor.
- 64. A method for imaging a mammalian body, comprising the steps of:
injecting into the body an echogenic microbubble composition comprising the vapor of a fluorocarbon that is a liquid at body temperature; and
ultrasonically imaging the microbubble composition in the body.

(Schutt Opposition 4, Paper No. 50, pages 1-2, Schutt '007 Prosecution History, Paper No. 3).

E. The Count

19. The interference was declared on July 14, 2000, (Paper No. 1), with Count 1 which reads as follows:

Count 1

Contrast media for ultrasound imaging comprising gaseous perfluorohexane.

(Notice Declaring Interference, Paper No. 1, p. 32).

20. The claims of the parties are as follows:

(i) The claims of the parties are:

Quay '854: 1-13
Schutt '007: 65-68

(ii) The claims of the parties which corresponded to Count 1 are:

Quay '854: 10-13
Schutt '007: 65-68

(iii) The claims of the parties which did not correspond to Count 1 are:

Quay '854: 1-9
Schutt '007: None

(Paper No. 1, p. 32).

21. Quay '854 claims 10-13 and Schutt '007 claims 65-68 are identical. Quay '854 claims 10-13 (and Schutt '007 claims 65-68) read as follows:

10. Contrast media for ultrasound imaging comprising gaseous perfluorohexane.

11. The contrast agent of claim 10 wherein a portion of said perfluorohexane is present as microbubbles suspended in a carrier.

12. The contrast agent of claim 11 wherein said carrier is an aqueous liquid.

13. The contrast agent of claim 11 wherein a portion of said microbubbles are less than 8 microns in diameter.

(QX 2009, claims 10-13 and Schutt's Clean Copy of Claims, Paper No. 11, p. 1).

22 Schutt has proposed adding claim 69 to the Schutt '007 application. Proposed claim 69 reads as follows:

69. Contrast media for ultrasound imaging comprising microbubbles comprising a mixture of gases comprising gaseous perfluorohexane.

(Schutt Preliminary Motion 4, Paper No. 42, p. 4).

II. Opinion

A. Overview of Preliminary Motions

There are thirteen pending preliminary motions. In particular, Schutt has four pending preliminary motions (Schutt Preliminary Motions 1-4) whereas Quay has nine pending preliminary motions (Quay Pending Preliminary Motions 1-8).²

Generally, Schutt's preliminary motions involve adding proposed claim 69 to Schutt's '007 application (Schutt Preliminary Motions 3 and 4) and raising questions concerning Quay's compliance with 35 U.S.C. §112, first paragraph, specifically, written description and enablement. (Schutt Preliminary Motion 1). Additionally, Schutt has filed Schutt Preliminary Motion 2 requesting that Quay's claims be held unpatentable under 35 U.S.C. §102(e), however, this motion appears to require a finding that Quay's corresponding claims lack written descriptive support in its earlier filed application.

Quay has filed a variety of motions. Foremost, Quay has alleged that Schutt's claims are unpatentable under 35 U.S.C. §112, first paragraph as they lack sufficient written description

²As noted by Quay in its index of motions, Quay has filed two distinct preliminary motions with the number "8." The first Quay Preliminary Motion 8 is for benefit of an earlier filed application whereas the second Quay Motion 8 is a Miscellaneous Motion to suppress evidence.

(Quay Preliminary Motion 4) and that Schutt's claims are unpatentable over Schutt's "admissions" of prior art (Quay Preliminary Motions 2 and 3). Quay has also filed preliminary motions seeking to substitute a count (Quay Preliminary Motion 7) and to declare an additional interference (Quay Preliminary Motion 5). Additionally, Quay has moved for priority benefit of its earlier applications (Quay Preliminary Motions 1 and 8). Lastly, Quay Preliminary Motion 8 moves to suppress portions of Schutt's "Second 37 CFR 1.639(b) Declaration of Alexey Kabalnov" (SX 1019).

As apparent from the Oral Hearing, a key question in this interference is whether either party has a patentable claim that corresponds to the Count. Specifically, Quay Preliminary Motion 4 and Schutt Preliminary Motion 1 allege that the opposing parties corresponding claims are unpatentable for lack of written description. Moreover, Schutt's proposed claim 69 is attacked on a similar basis. As discussed in detail below, we find that both Quay's and Schutt's corresponding claims and proposed claims are unpatentable for a lack of an adequate written description.

1. Schutt Preliminary Motion 1

Schutt Preliminary Motion 1 requests judgment that Quay claims 10-13 be found unpatentable under 35 U.S.C. § 112, first paragraph. Specifically, Schutt alleges that Quay claims 10-13 fail to comply with the written description requirement and the enablement requirement of 35 U.S.C. § 112, first paragraph. (Schutt Preliminary Motion 1, Paper No. 27, p. 1).

a. Written Description Analysis of Quay Claims 10-13

While the specifics of the cases concerning adequate written description vary, the cases agree that the inquiry is *factual* and must be assessed on a *case-by-case* basis. Moreover, because of the fact-sensitive nature of the written description inquiry, the Federal Circuit has advised against misapplication of precedent in this area. See, *Union Oil Co. of California v. Atlantic Richfield Co.*, 208 F.3d 989, 1000, 54 USPQ2d 1227, 1235 (Fed. Cir. 2000); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991); and, *In re Driscoll*, 562 F.2d 1245, 1250, 195 USPQ 434, 438 (CCPA 1977).

At the outset, compliance with the written description requirement of 35 U.S.C. §112, first paragraph is as of the filing date of the application relied on. *Reiffin v. Microsoft*, 214 F.3d 1342, 54 USPQ2d 1915 (Fed. Cir. 2000) (If claims to subject matter in later-filed application are not supported by ancestor application in terms of 35 U.S.C. §112, first paragraph, they are simply denied benefit of earlier filing date, not invalidated. Thus, for purposes §112, first paragraph, earlier specifications are relevant only when the benefit of an earlier filing date is sought under 35 U.S.C. §120.); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116.

The purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by the inventor. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. The inventor can demonstrate possession by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. The inventor, however, needs to show that the inventor was "in possession" of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious. *Lockwood v. American Airlines*,

Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

The disclosure as originally filed does not have to provide *ipsis verbis* support for the claimed subject matter at issue. *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000); *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570, 39 USPQ2d 1895, 1904 (Fed. Cir. 1996). Rather, if the written description does not use precisely the same terms used in a claim, the question then is whether the specification directs or guides one skilled in the art to the subject matter claimed such that the specification reasonably conveys to those skilled in the art that the inventor invented what is claimed. *See, e.g., Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570, 39 USPQ2d 1895, 1904 (Fed. Cir. 1996); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116; *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989).

Additionally, claims may be no broader than the supporting disclosure. As stated in *Gentry Gallery*:

In sum, the cases on which Gentry relies do not stand for the proposition that an applicant can broaden his claims to the extent that they are effectively bounded only by the prior art. Rather, they make clear that claims may be no broader than the supporting disclosure, and therefore that a narrow disclosure will limit claim breadth.

Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1480, 45 USPQ2d 1498, 1503 (Fed. Cir. 1998). Thus, in general terms, *Gentry* held that patent claims lack sufficient written description if they omit an element that a person skilled in the art would understand as essential to the originally disclosed invention. *See id.* at 1480.

Quay does not have *ipsis verbis* support for its claimed gaseous perfluorohexane contrast media. In particular, the Quay '085 application, from which the Quay '854 patent issued, does

not refer to, or mention perfluorohexane gas.³ The only recitation of perfluorohexane in the Quay '085 application occurs in Example 6 where it is in liquid form and used as a comparative compound. (For ease of reference see the Quay '854 patent, QX 2001, Example 6). Indeed, the Quay '085 application teaches that a dispersion of perfluorohexane was undetectable by ultrasound scanning. (QX 2001, Example 6). Based upon the comparative testing, Quay '854 concludes that a high Q value and a gaseous state at the body temperature of the organism being scanned is necessary for a substance to be effective as an ultrasound contrast agent. (QX 2001, Example 6, lines 34-38).

Quay argues that Example 6 is a "written description of the use of perfluorohexane as a ultrasound contrast enhancing agent" in a gaseous microbubble. (Quay Opposition 1, Paper No. 45, p. 8). As basis for this interpretation of Example 6, Quay relies on a Declaration of Dilip M. Worah ("Worah Declaration"). (QX 2022). The Worah Declaration, however, fails to explain how Mr. Worah reached, or the underlying basis for, this conclusion. Nothing in our rules or in our jurisprudence requires us to credit the unsupported assertions of an expert witness. *Cf. Rohm & Hass Co. v. Brotech Corp.*, 127 F.3d 1089, 1092, 44 USPQ2d 1459, 1462 (Fed. Cir. 1997). See also § 42 of the Standing Order (Paper 1, page 22) entered in this interference. Lacking any detailed analysis of Quay's Example 6, we decline to credit Mr. Worah's unsupported and unusual interpretation of Quay Example 6. Specifically, Example 6 does not mention the term "gaseous" or even "vapor" when discussing perfluorohexane. As such, Quay Example 6 does not provide written descriptive support for the claimed "gaseous perfluorohexane" contrast media.

³Quay '854 does recite the term "gaseous perfluorohexane" in claims 10-13, its abstract and in its title. These recitations, however, were added by amendment well after the application had been filed with the Patent & Trademark Office.

In addition to lacking *ipsis verbis* support, Quay '085 fails to guide one skilled in the art to the claimed "gaseous perfluorohexane" contrast media. Quay '085 provides no suggestion to one skilled in the art that the microbubbles of the invention may be prepared with compounds that are liquid at the temperature of the organism being scanned. Moreover, Quay '085 does not mention using at least one gas in combination with a vapor arising from a vapor/liquid equilibrium. Indeed, Example 6 would appear to lead one skilled in the art away from the use of compounds, such as perfluorohexane, that have a boiling point higher than the temperature of the organism being scanned. Furthermore, even though Quay '085 provides a list of 180 gases that have the "especially promising" Q value of greater than 5, Quay never mentions gaseous perfluorohexane as a suitable component for an ultrasound contrast media. (QX 2001, Table IV)

Schutt has demonstrated that Quay claims 10-13 are unpatentable to Quay as Quay lacks written descriptive support for the claimed gaseous perfluorohexane contrast media. As such, Schutt Preliminary Motion 1 is *granted*.

b. Enablement Analysis for Quay Claims 10-13

The enablement requirement is separate and distinct from the written description requirement of §112, first paragraph. Thus, a specification may enable one skilled in the art to make and use an invention and yet still not describe the invention. *Vas-Cath*, 935 F.2d at 1562-1563, 19 USPQ2d at 1116-1117. Accordingly, our decision that Quay claims 10-13 lack written descriptive support is not dispositive as to whether or not Quay claims 10-13 are enabled. Yet, as

agreed to by Schutt's counsel,⁴ this issue is rendered *moot* by our decision that Quay claims 10-13 are unpatentable to Quay for lack of written descriptive support.

2. Quay Preliminary Motion 1

Quay Preliminary Motion 1 moves to be accorded priority benefit of an earlier filed parent application. Specifically, Quay seeks priority benefit of the September 2, 1992 filing date of Quay, U.S. Application 07/936,011 (Quay '011). (Quay Preliminary Motion 1, Paper No. 17, pages 1-2).

According to Quay, the Quay '854 patent and the Quay '011 application contain identical disclosures as the Quay '854 patent is a Rule 1.60 divisional of the Quay '011 application. (Paper No. 17, p. 3). As the Quay '854 patent and the Quay '011 application contain the same disclosure, Quay states that it is "ipso facto" that Quay claim 10 is supported by the earlier filed Quay '011 application. (Paper No. 17, p. 3). Furthermore, Quay cites a statement made by Quay during the prosecution of the Quay '854 patent that cites Quay Example 6 as providing written descriptive support for the claimed "gaseous" perfluorohexane. (Paper No. 17, p. 5).

For Quay to have benefit of the earlier filing dates, Quay must demonstrate that its earlier applications constituted a constructive reduction to practice of the subject matter of the count.

⁴ Judge Tierney: Is it possible that we were to decide your Motion 1 and grant it on the basis of written description and not reach it on the enablement issue?

Mr. Rollins: Absolutely. That's possible and that's great with us. I have no problem with that. It doesn't enable. It doesn't describe, but we don't care which bullet gets it.

(July 18, 2001 Oral Hearing Transcript, p. 48, lines 13-21).

Credle v. Bond, 25 F.3d 1566, 1570, 30 USPQ 1911, 1914 (Fed. Cir. 1994). For an earlier-filed application to serve as constructive reduction to practice, “the applicant must describe the subject matter of the count in terms that establish that he was in possession of the later-claimed invention, including all of the elements and limitations presented in the count, at the time of the earlier filing.” *Hyatt v. Boone*, 146 F.3d 1348, 1353-54, 47 USPQ2d 1128, 1131 (Fed. Cir. 1998). Moreover, “it is insufficient as written description, for purposes of establishing priority of invention, to provide a specification that does not unambiguously describe all limitations of the count.” *Id.*

Quay states that if Schutt Motion 1 is granted, i.e., that Quay claims 10-13 are unpatentable to Quay under 35 U.S.C. § 112, first paragraph, then Quay Preliminary Motion 1 for priority benefit becomes moot. (Quay Reply 1, Paper No. 61, p. 4). Specifically, Quay claim 10 and the count are identical. Thus, as moving party, it is Quay’s burden to demonstrate the its earlier Quay ‘011 application contains a constructive reduction to practice of the subject matter of the count, i.e., Quay claim 10. 37 CFR § 1.637(a). Quay has failed to satisfy this burden. Specifically, Quay has failed to demonstrate that the Quay ‘011 application contains a description of “gaseous” perfluorohexane in a contrast media. As Schutt Preliminary Motion 1 is granted, and as Quay has failed to satisfy its burden with respect to Quay Preliminary Motion 1, Quay Preliminary Motion 1 is *denied*.

3. Schutt Preliminary Motion 2

Schutt Preliminary Motion 2 requests judgment that Quay claims 10-13 be found unpatentable under 35 U.S.C. § 102(e) over Schutt’s U.S. Patent 5,639,443. (Schutt Preliminary

Motion 2, p. 1). Specifically, Schutt '443, having an effective filing date of July 30, 1993, is said to be available as prior art for Quay claims 10-13.

Quay's parent applications are said to have an identical disclosure to that of the Quay '854 patent. Thus, our decision that Quay claims 10-13 lack written description in the Quay '854 patent compels a conclusion that these claims do not have sufficient written description in Quay's parent patent applications. Accordingly, Quay claims 10-13 do not receive the 35 U.S.C. §120 filing date benefits for Quay's parent applications. *Applied Materials Inc. v. Advanced Semiconductor Materials*, 98 F.3d 1563, 1579, 40 USPQ2d 1481, 1494 (Fed. Cir. 1996) (To secure the benefit of the filing date of an earlier filed ("parent") application, 35 U.S.C. §120 requires that the claimed invention be described in the manner provided by the first paragraph of §112, which requires 1) a written description of the invention, 2) enablement, and 3) disclosure of the best mode for practicing the invention.). Lacking benefit under 35 U.S.C. §120, Quay's effective date of filing for claims 10-13 is, at best, the filing date of the Quay '085 application, i.e., January 30, 1995. As such, Schutt '443 is available as prior art to Quay '854 under 35 U.S.C. § 102(e).

Schutt '443 describes the use of microbubbles as ultrasound contrast agents. (QX 2009, abstract). Schutt '443 Example 1 contains the following description of an ultrasound contrast agent:

Microbubbles with an average number weighted size of 5 microns were prepared by sonification of an isotonic aqueous phase containing 2% Pluronic F-68 and 1% sucrose stearate as surfactants, air as a modifier gas and perfluorohexane as the gas osmotic agent.

(QX 2009, Example 1).

The Schutt '443 disclosure anticipates Quay claims 10-13. Specifically, Schutt teaches a modifier gas in combination with perfluorohexane as an osmotic gaseous agent (Quay claim 10) in a microbubble that is suspended in an aqueous phase (Quay claims 11 and 12) where the microbubble has a weighted size of 5 microns (Quay claim 13). (Compare QX 2009, Example 1 with Quay '854 claims 10-13). As Schutt '443 anticipates Quay claims 10-13 under 35 U.S.C. § 102(e), Schutt Preliminary Motion 2 is *granted*.

4. Quay Preliminary Motion 4

Quay Preliminary Motion 4 moves for judgment that Schutt claims 65-68 are unpatentable for failure to satisfy the written description of 35 U.S.C. § 112, first paragraph. In particular, Quay alleges that Schutt claims 65-68 are directed to an invention "that is entirely different from any invention described in the Schutt specification." (Quay Preliminary Motion 4, Paper No. 21, p. 2).

According to Quay, Schutt's invention is based upon the partial pressures of a primary gas and a secondary gas osmotic agent and the regulated osmotic diffusion of the primary gas through a membrane which is essentially impermeable to the secondary gas osmotic agent. (Paper No. 21, p. 3). Quay states that the Schutt invention is "an elaborate and complex concept whose principle feature relies on osmosis and osmotic principles to control the size of microbubbles by means of osmotic diffusion of the contrast enhancing gas between the inside of the microbubble and the liquid carrier." (Paper No. 21, p. 5).

In support of its position, Quay cites numerous comments in the Schutt specification and prosecution history that are said to demonstrate that the Schutt invention relates to "osmotically

stabilized microbubbles” having a mixture of a modifier gas and a gas osmotic agent. For example, Quay cites Schutt’s comment that the Schutt invention is directed to:

[O]smotically stabilized microbubbles containing a gas mixture having specified molar ratios and/or partial pressures contained within a spherical structure such that the gas osmotic agent counteracts the pressure exerted on the bubble by the surrounding bubble membrane.

(Paper No. 21, pages 8-9 quoting from an Amendment, Paper No. 8 in Schutt Application 08/099,951). Quay concludes that there is no teaching or suggestion in the Schutt specification for merely claiming microbubbles comprising gaseous perfluorohexane. (Paper No. 21, p. 11).

Schutt argues that both the specification and “original” claims 62-64 provide written descriptive support for the claimed invention. We are not convinced that the Schutt ‘007 specification provides support for the invention of Schutt claims 65-68. Moreover, Schutt claims 62-64 are not “original” claims and are not a part of the originally filed ‘007 specification.

a. Schutt Claims 65-68 Are Not Supported by Schutt’s Specification

Schutt’s specification carefully and painstakingly describes the use of osmotic gas agents that are combined with modifier gases to form stabilized ultrasound contrast enhancement agents that are said to have prolonged longevity in vivo. For example, under the heading “Summary of the Invention,” Schutt states that the “present invention” involves:

... virtually any conventional microbubble formulation in conjunction with an entrapped gas or gas mixture that is selected based upon consideration of partial pressures of gases both inside and outside the bubble, and on the resulting differences in gas osmotic pressure that oppose bubble shrinkage.

(QX 2009, col. 2, lines 53-57). Specifically, in an effort to stabilize the bubbles, Schutt’s gas filled microbubble preparations are said to comprise a mixture of a *first* gas or gases and a *second* gas or gases within generally spherical membranes with the terms “gas” and “vapor”

being used interchangeably. (QX 2009, col. 2, line 65 to col. 3, line 1 and col. 6, lines 8-9).

Again, under the heading "Summary of the Invention," Schutt '007 defines the first and second gases as follows:

[T]he first gas and the second gas are respectively present [1] in a molar ratio of about 1:100 to about 1000:1, and wherein [2] the first gas has a vapor pressure of at least about (760-x) mm Hg at 37 °C., where x is the vapor pressure of the second gas at 37 °C., and wherein [3] the vapor pressure of each of the first and second gases is greater than about 75 mm Hg at 37 °C., with the proviso that [4] the first gas and the second gas are not water vapor.

(QX 2009, col. 3, lines 1-8, bolded numbers added for emphasis). Moreover, Schutt states that a "major aspect" of the invention is "the use of combinations of gases to harness or cause differentials in partial pressures and to generate gas osmotic pressures, which stabilize the bubbles." (QX 2009, col. 13, lines 35-39).

Schutt's '007 specification fails to reasonably convey to those skilled in the art that Schutt invented what is claimed. For example, Schutt's specification does not reasonably convey that Schutt invented an ultrasound contrast agent composition having gaseous perfluorohexane as its only gas. Similarly, Schutt's specification does not reasonably convey that Schutt invented an ultrasound contrast agent composition having gaseous perfluorohexane in combination with any other gas in any and all proportions and without regard to their respective vapor pressures. Moreover, Schutt's specification does not reasonably convey that Schutt invented an ultrasound contrast agent composition having a mixture of gaseous perfluorohexane and a second gas, where the second gas is the vapor of the surrounding liquid medium.

Schutt acknowledges that its specification describes a "complex invention" of using a mixture of gases to stabilize microbubbles. (Schutt Opposition 4, Paper No. 50, p. 5). Schutt also acknowledges that the various arguments made during the prosecution of Schutt's parent

patent application were directed to more complex inventions than that defined by Schutt claims 65-68. Yet, Schutt argues that the description and arguments regarding the complex invention do not detract from Schutt's description of "how to use gaseous perfluorohexane in microbubbles in any manner to enhance ultrasound imaging."⁵ (Paper No. 50, pages 5-6). Schutt, however, fails to sufficiently identify where the "separate" gaseous perfluorohexane invention is described in the Schutt specification.

At Oral Hearing, counsel for Schutt attempted to reconcile the differences between the presently claimed invention and the teachings of Schutt's specification. In particular, Schutt requested that we construe claims 65-68 as possessing any necessary limitations that make the claimed invention operable. For example:

Judge McKelvey:	Doesn't your invention seem to involve a combination of gases? So how do we get off just claiming the hexane embodiment by itself?
Mr. Rollins:	Hexane embodiment by itself? Well, I think, again, if you look back to the Schutt specification, it makes very clear that the only way that you can use perfluorohexane or a material that is normally liquid at body temperature is to incorporate the vapor during the manufacturing and to add mixture with a gas that is a suitable carrier such as air, nitrogen, CO ₂ or something of that sort.
Judge Schafer:	If that's the case, then how do you have basis for just claiming perfluorohexane?
Mr. Rollins:	I think it has to be read in light of the specification.
Judge Tierney:	You're requiring us to read in certain limitations that are not explicitly present in Claim 10 [sic, Schutt claim 65]?
Mr. Rollins:	That's one way of looking at it. I guess the other way of looking at it is sort of as in <i>Lee v. McIntyre</i> , is that you construe the claim to give it a construction that is its broadest reasonable construction and not give it a narrower construction.

⁵We note that Schutt appears to acknowledge that its written description is, at a minimum, directed to microbubble compositions. Yet, while Schutt claims 66-68 literally require the presence of microbubbles, claim 65 does not.

Judge Schafer: If we did that, what would be the limits of its broadest reasonable construction? What would be put in the claim?
Mr. Rollins: Our Motion 4 puts in what I think would be a more suitable claim [proposed claim 69].

(Paper No. 95, p. 29, line 21 to p. 31, line 12). Additionally, it was stated:

Judge Tierney: Could you clarify for me what are the limitations that will make Claim 65 operable?
Mr. Rollins: That make Claim 65 operable? I think they [sic, there] are inherent limitations provided by the specification.

(Paper No. 95, p. 52, lines 8-13). Furthermore, counsel stated:

Judge Tierney: Is it your position then that Claim 65 which reads that contrast media for ultrasound imagining [sic, imaging] comprising gaseous perfluorohexane should be construed as encompassing any operable embodiment and excluding all inoperable embodiments?
Mr. Rollins: To the extent there are inoperable embodiments. If you read it as saying you can have only perfluorohexane gas in the media; in other words, it's comprising only perfluorohexane, that's inoperable.

(Paper No. 95, p. 55, lines 4-16). Similarly:

Judge Tierney: Your '443 [patent] specification also requires - - appears to require specific vapor pressures for the first and second gases. Is that a correct statement?
Mr. Rollins: They're very broad. Yes, that's correct.
Judge Tierney: If you find it [perfluorohexane] as the first gas, doesn't that necessarily imply certain limitations on the second gas?
Mr. Rollins: Yes. However, if the first gas is perfluorohexane, you get certain limitations on the amount. From that, if you consider perfluorohexane to be the second gas, you get a different amount. I believe the sum of the amounts would be any amount that you might come up with and remain a mixture.
Judge Tierney: Are those limitations required by any of your Claims 65 through proposed Claim 69?
Mr. Rollins: No.
Judge Tierney: Aren't your claims broader than what you're teaching?
Mr. Rollins: Only to the extent that they do not exclude expressly inoperable embodiments.

(Paper No. 95, p. 36, lines 4-9 and p. 37, line 5 to p. 38, line 2).

We decline Schutt's invitation to read the specification's "inherent" limitations into Schutt claims 65-68. Such a claim construction would obviate Schutt's need to properly claim its invention. As stated by the Federal Circuit:

When claim construction is required, claims are construable, as above indicated, in light of the specification, *United States v. Adams*, 383 U.S. 39, 49, 148 USPQ 479, 482 (1966), yet "[t]hat claims are interpreted in light of the specification does not mean that everything expressed in the specification must be read into all the claims." *Raytheon Co. v. Roper Corp.*, 724 F.2d at 957, 220 USPQ at 597. If everything in the specification were required to be read into the claims, or if structural claims were to be limited to devices operated precisely as a specification-described embodiment is operated, there would be no need for claims. Nor could an applicant, regardless of the prior art, claim more broadly than that embodiment. Nor would a basis remain for the statutory necessity that an applicant conclude his specification with "claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112. It is the claims that measure the invention. *Aro Mfg. Co., Inc. v. Convertible Top Replacement Co., Inc.*, 365 U.S. 336, 339, 128 USPQ 354, 356-57 (1961); *Bandag, Inc. v. Al Bolser's Tire Stores, Inc.*, 750 F.2d 903, 922, 223 USPQ 982, 996 (Fed. Cir. 1984); *Jones v. Hardy*, 727 F.2d 1524, 1528, 220 USPQ 1021, 1022 (Fed. Cir. 1984).

SRI Int'l v. Matsushita Elec., 775 F.2d 1107, 1121, 227 USPQ 577, 585 (Fed. Cir. 1985) (in banc).

Even if we were to accept Schutt's invitation to read in those limitations necessary for "operability," it is unclear what counsel for Schutt would have us deem "operable." For example, it is unclear whether Schutt desires a claim construction that would limit its invention to those embodiments that would be effective for imaging a human aorta as opposed to imaging any animal (QX 2009, col. 5, line 63 to col. 6, line 4), such as a guinea pig or an elephant. Moreover, it is unclear on this record what limitations in the specification are "expressly inoperable embodiments."

We take this opportunity to remind Schutt of the Federal Circuit's statement that:

Claims which include a substantial measure of inoperatives, as evidenced by the Gedge, Benson, and Ohren declarations, are fairly rejected under 35 U.S.C. § 112. *In re Cook*, 439 F.2d 730, 735, 169 USPQ 298, 302 (CCPA 1971); see *Atlas Powder Co. v. E.I. DuPont DeNemours & Co.*, 750 F.2d 1569, 1576-77, 224 USPQ 409, 414 (Fed. Cir. 1984). As footnoted in *In re Cook*, "during the prosecution of patent applications * * * an applicant is still in a position to amend his claims to exclude inoperative subject matter". *In re Cook*, 439 F.2d at 734 n.3, 169 USPQ at 302 n.3; see 439 F.2d at 734 n.4, 169 USPQ at 302 n.4. The rejection under section 112 is affirmed.

In re Corkill, 771 F.2d 1496 at 1501, 226 USPQ 1005 at 1009 (Fed. Cir. 1985).

As set forth above, Schutt's specification fails to guide one skilled in the art to the presently, and broadly, claimed invention. Schutt, however, also argues that its original disclosure is not limited to the specification, but includes claims 62-65. These claims, however, are not "original" claims and are not considered part of the "original" disclosure.

b. Schutt Claims 62-64 Are Not "Original" Claims

The Schutt '007 application was filed on January 17, 1997 as a Rule 1.60(b) continuation application of the pending prior Schutt '447 application, filed on March 16, 1995 which was said to be a continuation of Schutt application 08/099,951, filed on July 30, 1993. (Schutt Continuation Transmittal Form, QX 2011, p. 1).

Rule 1.60(b) allowed an applicant to omit the signing of the oath or declaration in a continuation application if several conditions were met. For example, conditions 2 and 4 of Rule 1.60(b) provided that:

- (2) Applicant indicates that the application is being filed pursuant to this section and files a true copy of the prior complete application as filed including the specification (with claims), drawings, oath or declaration showing the signature or an indication it was signed, and any amendments referred to in the oath or declaration filed to complete the prior application;
- (4) The application is filed before the patenting, or abandonment of, or termination of proceedings on the prior application. The copy of the prior application must be accompanied by a statement that the application papers filed are a true copy of the prior complete application. Such statement must be by the applicant or applicant's attorney or agent and must be a verified statement if made by a person not registered to practice before the Patent and Trademark Office. Only amendments reducing the number of claims or adding a reference to the prior applications (§1.78(a)) will be entered before calculating the filing fee and granting the filing date.

37 CFR § 1.60(b), 60 FR 20224, Apr. 25, 1995, emphasis added.

Consistent with Rule 1.60(b), Schutt provided the Patent & Trademark Office ("PTO") with a complete copy of the earlier filed Schutt '447 application. The copy of the '447 application contained 61 claims. Of note, claims 1, 33, 37, 44 and 49 were independent claims. Claim 1 was directed to a specific stabilized gas filled microbubble preparation whereas claims 33 and 37 were directed to a kit for use in preparing microbubbles and claims 44 and 49 were directed to a method for forming microbubbles. Original claim 1 read as follows:

1. A stabilized gas filled microbubble preparation, comprising:
a mixture of a first gas or gases and a second gas or gases within generally spherical membranes to form microbubbles, wherein said first gas and said second gas are respectively present in a molar ratio of about 1:100 to about 1000:1, and wherein said first gas has a vapor pressure of at least about (760 - x) mm Hg at 37 °C, where x is the vapor pressure of the second gas at 37 °C, and wherein said vapor pressure of each of said first and second gases is greater than about 75 mm Hg at 37 °C, with the proviso that said first gas and said second gas are not water vapor.

As allowed under 37 CFR § 1.60(b), Schutt's transmittal form requested that claims 2-61 of the prior application be cancelled prior to calculating the filing fee. (QX 2011, p. 1). Accordingly,

only original claim 1 was pending in the '007 application prior to granting Schutt the January 17, 1997 filing date. 37 CFR § 1.60(b), 60 FR 20224, Apr. 25, 1995.

Concurrent with the filing of the Rule 1.60(b) application, Schutt filed a Preliminary Amendment that requested that the PTO cancel all original claims and “please add the following new Claims 62-64.” (Schutt '007, Preliminary Amendment, p. 1, emphasis added). Having accorded Schutt the January 17, 1997 filing date, Schutt's requested Preliminary Amendment was entered. The “new” claims added in the Preliminary Amendment, however, are not considered part of the original disclosure. As noted by Federal Circuit:

Although our decision assumes that Litton converted its Rule 60 continuation application and its preliminary amendment into a valid C-I-P application on the date Litton filed its C-I-P declaration, we understand PTO practice to require that any new matter must be added to a C-I-P application prior to filing, and not through amendment, cf., MPEP §608.04-(b) (a preliminary amendment does not enjoy any status as part of an original disclosure).

Litton Systems, Inc. v. Whirlpool Corp., 728 F.2d 1423, 1437-38, 221 USPQ 97, 105-106 (Fed. Cir. 1984). Lacking the status of “original” claims, Schutt claims 62-64 are not a part of the originally filed '007 specification.

Schutt argues that the subject matter of claims added to a continuing application by preliminary amendment has been considered by the Federal Circuit in *Hyatt v. Boone*, 146 F.3d 1348, 1355-1356, 47 USPQ2d 1128, 1132-33 (Fed. Cir. 1998). The decision in *Hyatt*, however, involved a different set of facts than those presented in the filing of Schutt's '007 application. Specifically, in *Hyatt* it was alleged that Boone's second and eighth applications were filed under the streamlined provisions of Rule 1.60 with photocopies of the prior specification and oath and contained amended claims. The primary issue raised in *Hyatt* was the alleged discontinuity in the chain of priority for Boone's applications. Indeed, unlike the present interference, the decision in

Hyatt did not involve a question of whether claims filed in a preliminary amendment are considered original claims for purposes of the written description requirement. Accordingly, *Hyatt* is no basis for a conclusion that Schutt claims 62-64 are “original” claims.

Schutt also argues that even if the claims presented in Schutt’s Preliminary Amendment were considered to be new matter, it would only result in (1) a new oath or declaration being submitted and (2) the designation of Schutt’s ‘007 application be changed to a continuation-in-part (“CIP”) application. (Schutt Opposition 4, Paper No. 50, p. 3). Schutt, however, has not moved to file, or attempted to file, a new oath or declaration.

As with *Gentry Gallery*, Schutt’s narrow written description does not support its newly and broadly claimed invention. As Schutt’s originally filed disclosure fails to convey to a person skilled in the art that Schutt invented the claimed contrast media compositions of Schutt claims 65-68, Quay Preliminary Motion 4 is *granted*.

5. Schutt Miscellaneous Motion 3 and Preliminary Motion 4

Schutt Miscellaneous Motion 3 requests permission to file a belated motion to add a claim to Schutt’s involved application. (Schutt Preliminary Motion 3, Paper No. 41, p. 1). Schutt’s Miscellaneous Motion 3 is unopposed. Based on the facts presented, Schutt Miscellaneous Motion 3 is *granted*.

Schutt Preliminary Motion 4 requests that new claim 69 be added to Schutt’s involved ‘007 application and that new claim 69 be designated as corresponding to Count 1. (Schutt Preliminary Motion 4, Paper No. 42, p. 1). Schutt proposes to add new claim 69 as “Schutt wishes to present a claim which does not run afoul even of Quay’s arguments under Gentry Gallery.” (Paper No. 42, p. 3).

Schutt's proposed new claim 69 reads as follows:

69. Contrast media for ultrasound imaging comprising microbubbles comprising a mixture of gases comprising gaseous perfluorohexane.

(Paper No. 42, p. 4). According to Schutt, proposed claim 69 differs from the count in "requiring," rather than "permitting," an additional gas in admixture with gaseous perfluorohexane. (Paper No. 42, p. 4).

Quay opposes the addition of proposed claim 69 on the grounds that the claim lacks sufficient written descriptive support in the Schutt '007 specification. According to Quay, Schutt's described invention relates to the formation of contrast agents "based on the partial pressures of a primary gas and a secondary gas osmotic agent, and the regulated osmotic diffusion of the primary gas through a membrane which is essentially impermeable to the secondary gas osmotic agent." (Quay Opposition 4, Paper No. 55, p. 4).

While it is true that a claimed invention need not be limited to a preferred embodiment, the claim must be supported by the originally filed disclosure. If the original disclosure narrowly defines the invention, it follows that the claim must also be sufficiently narrow. *Gentry Gallery*, 134 F.3d at 1480, 45 USPQ2d at 1503.

In support of proposed claim 69, Schutt directs our attention to several passages in its '007 application. For example, Schutt cites the following statement that appears under the heading "Summary of the Invention:"

The present invention also includes a method for forming microbubbles, comprising the steps of providing a first gas and a second gas, a membrane forming material, and a liquid, wherein the first gas and the second gas are present [1] in a molar ratio of about 1:100 to about 1000:1, and wherein [2] the first gas has a vapor pressure of at least about $(760-x)$ mm Hg at 37 °C., where x is the vapor pressure of the second gas at 37 °C., and wherein [3] the vapor pressure of each of the first and second gases is greater than about 75 mm Hg at 37 °C., with the proviso that [4] the first gas and the second gas are not water vapor, and

surrounding the first and second gases with the membrane forming material to form microbubbles in the liquid.

(Paper No. 42, p. 5, Schutt '007, p. 9, lines 3-15, numbers in bold added for ease of reference).

Given that Schutt directs us to this passage as descriptive support and that this citation falls under the heading "Summary of the Invention," a person of ordinary skill in the art would understand that these features, numbered 1 through 4, are essential to the described invention.

Schutt's '007 specification fails to reasonably convey to those skilled in the art that the Schutt invented the broadly claimed invention of proposed claim 69. As evident from above, Schutt's specification provides rather narrow description of the "inventive" stabilized microbubble formulations. For instance, as with claims 65-68, Schutt's specification does not reasonably convey that Schutt invented an ultrasound contrast agent composition having gaseous perfluorohexane in combination with any other gas in any and all proportions and without regard to their respective vapor pressures. Moreover, Schutt's specification does not reasonably convey that Schutt invented an ultrasound contrast agent composition having a mixture of gaseous perfluorohexane and a second gas, where the second gas is the vapor of the surrounding liquid medium. As Schutt has failed to identify sufficient written descriptive support for its proposed claim 69, Schutt Preliminary Motion 4 is *denied*.

6. Quay Preliminary Motions 2 and 3

Quay Preliminary Motion 2 moves for judgment that Schutt claims 65-68 are unpatentable to Schutt in view of Quay's PCT application PCT/US92/07250 ("Quay PCT").

(Quay Preliminary Motion 2, Paper No. 18, pages 1-2). Additionally, Quay Preliminary Motion 3 moves for judgment that Schutt claims 65-68 are unpatentable to Quay based upon Schutt's

"admission" that Quay is the prior inventor of the claimed subject matter. (Quay Preliminary Motion 3, Paper No. 19, pages 1-2).

According to Quay, the Quay PCT application contains an identical disclosure to that of the Quay '854 patent. (Paper No. 18, p. 5). Quay notes that, Schutt's '007 specification refers to the Quay PCT application under the heading "Background of the Art." (Paper No. 18, p. 3). Based upon Schutt's acknowledgment of the existence of Quay's PCT application, Quay concludes that Schutt has admitted that Quay's PCT is: (1) prior art to Schutt; and (2) that Quay is the prior inventor of the subject matter of the interference. (Paper No. 18, p. 4 and Paper No. 19, p. 4).

As we have already decided that Schutt claims 65-68 are unpatentable to Schutt under 35 U.S.C. § 112, first paragraph, written description, the patentability issues raised by these motions are *moot*.

7. Quay Preliminary Motions 5 and 6

Quay Preliminary Motion 5 moves for an additional interference between Quay Application No. 09/688,117 and Schutt '007. (Quay Preliminary Motion 5, Paper No. 22, pages 1-2 and Quay Supplement to Preliminary Motion 5, Paper No. 36, p. 2). Quay Preliminary Motion 5 is a contingent motion. The motion is contingent upon two conditions: (1) that Quay is not entitled to Quay claims 10-13; and (2) that Schutt is entitled to Schutt claims 65-68. As we have found that Schutt claims 65-68 are unpatentable to Schutt, this motion is *moot*.

Quay Preliminary Motion 6 requests that Quay Application No. 09/688,117 be accorded priority benefit of several earlier filed Quay applications. As the relief requested in Quay Preliminary Motion 6 is contingent upon the relief granted in Quay Preliminary Motion 5, Quay

Preliminary Motion 6 is *moot*.

8. Quay Preliminary Motions 7 and 8

Quay Preliminary Motion 7 moves to substitute proposed Count A for Count 1. (Quay Preliminary Motion 7, Paper No. 37, pages 1-2). This preliminary motion is said to be contingent upon the denial of Quay Preliminary Motion 4. As Quay Preliminary Motion 4 was granted, Quay Preliminary Motion 7 is *moot*.

Quay Preliminary Motion 8 moves for benefit of an earlier filed application. (Quay Preliminary Motion 7, Paper No. 38, pages 1-2). This preliminary motion is said to be contingent upon Quay Preliminary Motion 7. As the relief requested in Quay Preliminary Motion 8 is contingent upon the relief granted in Quay Preliminary Motion 7, Quay Preliminary Motion 8 is *moot*.

9. Quay Miscellaneous Motion 9 (Motion to Suppress)

Quay Miscellaneous Motion 9 moves to suppress a portion of Schutt's evidence. (As there are two motion "8's" we will refer to Quay's Miscellaneous Motion 8 to Suppress Evidence, Paper No. 80 as "Quay Miscellaneous Motion 9"). According to Quay, the Second Declaration of Alexey Kablanov (SX 1019) and the Supplemental Declaration of Alexey Kablanov (SX 1065) contain statements that lack foundation, were contradicted under cross-examination and/or are inadmissible as they are not relevant evidence. The requested suppression of Alexey Kablanov's Second Declaration and Supplemental Declaration is *moot* as we have not relied upon this declaration testimony.

III. Order

As apparent from our discussion above, neither party has any pending or proposed claim that is patentable to that party. This decision on motions thus becomes a final decision.⁶

Upon consideration of the record, and for the reasons given, it is:

ORDERED that Schutt Preliminary Motion 1 is *granted*.

FURTHER ORDERED that Quay Preliminary Motion 1 is *denied*.

FURTHER ORDERED that Schutt Preliminary Motion 2 is *granted*.

FURTHER ORDERED that Quay Preliminary Motion 4 is *granted*.

FURTHER ORDERED that Schutt Miscellaneous Motion 3 is *granted*.

FURTHER ORDERED that Schutt Preliminary Motion 4 is *denied*.

FURTHER ORDERED that Quay Preliminary Motion 2 is *denied*.

FURTHER ORDERED that Quay Preliminary Motion 3 is *denied*.

FURTHER ORDERED that Quay Preliminary Motion 5 is *moot*.

FURTHER ORDERED that Quay Preliminary Motion 6 is *moot*.

FURTHER ORDERED that Quay Preliminary Motion 7 is *moot*.

FURTHER ORDERED that Quay Preliminary Motion 8 is *moot*.

FURTHER ORDERED that Quay Motion 9 (motion to suppress evidence) is *moot*.

FURTHER ORDERED that Junior Party Quay is not entitled to a patent containing claims 10-13 of Quay, U.S. Patent No. 5,558,854. 35 U.S.C. § 112, first paragraph (lack of written description).

⁶Normally we would enter an Order to Show Cause as to why this interference should continue. At this juncture, however, the time for submitting additional evidence is past. As such, a response to an Order to Show Cause would in essence be a Request for Reconsideration.

FURTHER ORDERED that Senior Party Schutt is not entitled to a patent containing claims 65-68 of Schutt, U.S. Patent Application No. 08/785,007. 35 U.S.C. § 112, first paragraph (lack of written description).

FURTHER ORDERED that a copy of this final decision shall be placed and given a paper number in the file of Quay, U.S. Patent No. 5,558,854 and Schutt, U.S. Patent Application No. 08/785,007.

FURTHER ORDERED that if there is a settlement agreement, attention is directed to 35 U.S.C. § 135(c) and 37 CFR § 1.661.

meK
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UTILITY/DESIGN PATENT

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Applicant: Schmitt et al.

Title: Osmotically Stabilized Microbubble Preparations

☒ Amendment - transmitted in 2 pages (in duplicate)

☒ Amendment in 6 pages

☒ Exhibit A in 38 pages with 1 page cover sheet

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